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KIT AND METHOD FOR TREATING HOT FLASHES ASSOCIATED WITH
MENOPAUSE

BACKGROUND

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This invention relates generally to treating one or more symptoms associated with menopause in a menopausal woman. In particular, the invention relates to a kit and method for treating hot flashes in a menopausal woman.

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Typically, hot flashes associated with menopause have been treated with hormones. However, hormone therapy may be associated with numerous side effects. Thus, hormone therapy is not often recommended for the treatment of hot flashes in menopausal women. Alternatives in treating hot flashes are needed.

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U.S. Patent No. 4,900,554 discloses an adhesive device for application to body tissue to provide sustained drug release or to protect a body tissue, the device having an adhesive layer and a backing layer positioned over one side of the adhesive layer. The adhesive layer includes one or more acrylic acid polymers having adhesive properties upon dissolution or swelling in water, and at least one water insoluble cellulose derivative. The backing layer is water insoluble or sparingly water soluble.

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U.S. Patent No. 5,780,047 discloses a patch that comprises a water-soluble adhesive sheet, and a water-soluble protective material laminated thereon. The patch can be applied to the skin so as to exhibit warm-bathing effects on the application site.

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U.S. Patent Nos. 6,224,899; 6,228,376; and 6,524,612 disclose an adhesive cooling gel composition which contains a large amount of water and which provides a cooling effect

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and/or coolness-preserving effect, and a process for preparing the same. The composition comprises a polyacrylic acid compound, a polyvalent metal component and water, wherein the content of water is 75 to 95% by weight based on the cooling composition. Also disclosed are an adhesive cooling composition shaped into a sheet, and a process for preparing the adhesive cooling composition, the process being selected from processes given below in (1) to (3), each process including a step of mixing and dissolving the components of the composition and a deaerating step: (1) a process wherein an aqueous solution is deaerated and then the other components of the composition are mixed and/or dissolved; (2) a process wherein while an aqueous solution is deaerated, the other components of the composition are mixed and/or dissolved; or (3) a process wherein after the other components of the composition are mixed and/or dissolved, the obtained solution is deaerated.

U.S. Patent No. 5,956,963 discloses a wrist cooler that offers relief for hot flash symptoms of menopause and body overheating. The cooler includes chemical cooling pellets that remain in a solid state until broken. A woman experiencing symptoms such as menopausal hot flashes carries the cooler in her purse. When hot flashes occur, the cooler is removed from her purse, the pellets are broken and the cooler is slid onto her wrist. Once the flashes have subsided, the cooler is discarded. The cooler is easily transportable and provides for immediate relief, as there are no reusable cooling elements to be frozen or chilled.

U.S. Patent Publication No. 2003/0176904 discloses a self-adhering cotton fabric cold strip that is to be worn as a wrist band, or an ankle band. The self-adhering cotton fabric cold strip has an envelope defining a sealed cold strip volume. A cooling gelatinous material is positioned in the cold strip volume. A bandage sheet is fixed to the

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envelope. The bandage sheet defines a bandage adhesive for temporary adhesion of the cold strip to the skin surface of a user. The self-adhesive envelope contains a cooling gelatinous material which reduces the body temperature. The reduction of the body temperature brings relief that is convenient, portable, and lasts for hours. The cold strip is to be worn for a period of hours and is then disposed and replaced with another cold strip. The self-adhering cotton fabric cold strip will be produced with different colors of cloth.

In view of the disadvantages of hormone therapy, and the shortcomings associated with wrist or ankle cooling devices, such as the noticeable presence of the devices, improved treatments are needed to control and reduce hot flash symptoms in menopausal women.

SUMMARY

The present invention is generally directed to a non-hormonal treatment of hot flashes. A kit and method are described which involve placing a cooling device on an inconspicuous location, preferably on a torso and more preferably on an upper portion of a back of a woman who is experiencing a hot flash or who is prone to experiencing a hot flash. Although the exemplary embodiment of the invention is directed to placing the cooling device on the back of a woman, the cooling device may be placed at any hot flash origin site, or the site where the hot flash is felt first. Such origin sites can be any place on the body. For example, the origin site may be on the upper portion of a woman's body or a lower portion of a woman's body. In certain situations, the origin site is any location other than the wrists, ankles, or chest. In certain situations, the origin site is a location on a woman's stomach, in

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proximity to the elbow of the woman's arms, on the woman's neck, or on the woman's back.

5 In one embodiment, a kit for treating hot flashes associated with menopause in a woman comprises one or more cooling devices; and instructions for using the cooling device or devices. The instructions include directions to place the cooling device on the skin of a woman at a hot flash origin site, such as a location on her back, such as
10 between her shoulder blades, when a hot flash begins.

In another embodiment, a method for treating hot flashes comprises providing at least one cooling device; and instructing a woman to place the at least one cooling device
15 at a hot flash origin site, such as a location on her back, such as between the shoulder blades, when the hot flash begins.

Each and every feature described herein, and each and
20 every combination of two or more of such features, is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent. In addition, any feature or combination of features may be specifically excluded from
25 any embodiment of the present invention.

Additional advantages and aspects of the present invention are apparent in the following detailed description, drawings, and claims.
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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a kit for treating hot flashes.
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FIG. 2 is a top plan view of a cooling device provided in the kit of FIG. 1.

FIG. 3 is a bottom plan view of the cooling device of
5 FIG. 2.

FIG. 4 is a side view along line 4-4 of FIG. 3.

FIG. 5 is an illustration of two cooling devices
10 located on the back of a menopausal woman.

DETAILED DESCRIPTION

A kit for treating hot flashes associated with
15 menopause in a woman comprises at least one cooling device;
and instructions for using the cooling device. The
instructions include directions to place the at least one
cooling device on the skin of a woman at a hot flash origin
site when the woman experiences a hot flash, such as when a
20 hot flash begins.

Although the exemplary embodiment of the invention is
directed to placing the cooling device on the back of a
woman, the cooling device may be placed on any region of the
25 woman's body, for example, at any hot flash origin site, or
the site where the hot flash is felt first. Advantageously,
the cooling device is placed on a region of the woman's body
that is above the ankles and wrists, for example, at or
above the knees and elbows. In one embodiment, the cooling
30 device is placed on the woman's torso.

In one embodiment, the cooling device is placed on an
inconspicuous region of the woman's body, that is a region
of the woman's body that can carry the cooling device
35 without the cooling device being apparent to others. Since
the upper portion of a woman's chest is often exposed even

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when the woman is clothed, in one embodiment, the region of the woman's body which the cooling device is placed is other than the upper portion of the woman's chest.

Hot flash origin sites can be any place on the body. For example, the origin site may be on the upper portion of a woman's body or a lower portion of a woman's body. In certain situations, the origin site is any location other than the wrists, ankles, or chest. In certain situations, the origin site is a location on a woman's stomach, in proximity to the elbow of the woman's arms, on the woman's neck, or on the woman's back.

Typically, the cooling device is placed on the woman's body, for example, on the hot flash origin site, as soon as possible after a hot flash begins, such as within about five minutes from when a hot flash begins, for example, within about two minutes from when a hot flash begins.

In reference to the accompanying drawings, which are provided as example of one embodiment of the present invention, a kit 10 comprising a plurality of cooling devices 12, and instructions for use 14 is illustrated in FIG. 1. The kit 10 is in the form of a sealed package 16. Although two cooling devices 12 are illustrated in the kit 10, the kit 10 may include only one cooling device 12, or more than two cooling devices 12. In addition, each cooling device 12 may be provided in individual sealed packages provided with the sealed package 16.

The cooling device 12 of the kit 10 may be any suitable device configured to cool the skin of a woman experiencing a hot flash. For example, the cooling device 12 may be a device that can be placed in a freezer or refrigerator, and the like, and then can be removed and placed on the skin at a cooled temperature (e.g., a temperature below room temperature, such as below about seventy degrees

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Fahrenheit). One example of such a cooling device is an "ice-pack". Or, the cooling device 12 may be a device configured to cool the woman's skin by removing heat from the woman's skin, such as by evaporation.

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One example of a cooling device 12 is illustrated in FIG. 2. As illustrated, the cooling device 12 of FIG. 2 is symmetrical about an axis A. The cooling device 12 includes a first portion 22 and a second portion 24. The second portion 24 extends from the first portion 22. The first portion 22 has a width 22W, and the second portion 24 has a width 24W. The width 22W and the width 24W are substantially perpendicular to the axis A. The width 24W is illustrated as being smaller than the width 22W. The cooling device 12 is generally shaped as a T.

As shown in FIG. 3, the cooling device 12 comprises a cooling component 18 coupled to a substrate 20. The substrate 20 typically comprises a gas-permeable material, such as a natural or synthetic fiber material. In certain cooling devices, the substrate 20 consists comprises, consists essentially of, or consists of a cotton fiber sheet. The cooling component 18 is surrounded by a border 26 of the substrate 20. The border 26 is substantially free of the cooling component 18. In certain embodiments, the border 26 may include one or more adhesive regions effective in facilitating adhesion of the cooling device 12 on the woman's skin. The adhesive regions may include the same material of the cooling component 18, or may include other adhesive materials, such as topically acceptable glues, and the like.

FIG. 4 illustrates the thickness of the cooling device 12. The thickness of the cooling device 12 is determined by the thickness of the substrate 20 and the cooling component 18. Preferably, the thickness of the cooling device 12

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relatively small so that the cooling device 12 is not substantially visible through a woman's clothing when the device is placed on the woman's skin.

5 The cooling device 12 of the kit 10 may be an adhesive patch. The patch should be tacky or sticky enough to permit a woman to wear the cooling device on her skin for extended periods of time, if desired. For example, the patch may adhere to the woman's skin for more than one minute, and may
10 adhere to the woman's skin for six hours or more. In addition, the patch may be readhered to the skin after being used, if desired.

In one embodiment, the adhesive patch comprises,
15 consists essentially of, or consists of a water-containing gel. The gel may be coupled to a gas-permeable substrate, such as a fibrous material. For example, the adhesive patch may consist essentially of a water-containing gel coupled to
20 a cotton fiber sheet. The water containing gel may comprise a polyacrylic acid component. The water containing gel may have a water content from about 75% to about 95% by weight of the gel. One example of a cooling device 12 which comprises a water-containing gel coupled to a gas permeable substrate is disclosed in U.S. Patent Nos. 6,224,899;
25 6,228,376, and 6,524,612, and which is publicly available under the tradename Be Kool® (Kobayashi Pharmaceutical Co., LTD. Corporation, Japan).

The cooling device 12 may be substantially free of a
30 pharmaceutical agent, such as a pharmaceutical agent used in the treatment of menopause symptoms, such as hot flashes.

As shown in the drawings, the cooling device 12 is approximately "T-shaped". The cooling device may have a
35 width, such as the width 22W, of about 3 inches, a height of

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about 2 inches, and a thickness of about 1/8 of an inch.
The width 24W may be about 1 inch.

5 The instructions 14 of the kit 10 may include
directions to apply the at least one cooling device 12 to
the desired region of skin within the first five minutes of
feeling a hot flash. Directions may be in the form of
words, pictures, and combinations thereof. The instructions
14 may also include directions to apply the at least one
10 cooling device to a region located between the C3 vertebrae
and the T6 vertebrae. While not wishing to be bound by any
particular theory or mechanism of action, it has been
discovered that placing the cooling device 12 in a region of
the upper back between the shoulder blades can substantially
15 alleviate hot flashes associated with menopause. In certain
situations, it has been found that placement of a cooling
device 12 at a region in proximity to the cervical and
thoracic vertebrae at the onset of a hot flash can
effectively prevent the hot flash from spreading throughout
20 a woman's body.

As shown in FIG. 5, the cooling device 12 is placed in
an upper region of a woman's back, such as a region between
the woman's shoulder blades.

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In accordance with the present invention, a method of
treating hot flashes associated with menopause comprises
providing at least one cooling device, such as the cooling
devices disclosed herein; and instructing a woman to place
30 the at least one cooling device on her skin at a location
between her shoulder blades when a hot flash begins. The
cooling device or cooling devices may be placed in one or
two regions on the upper portion of the woman's back between
and up from the shoulder blades. For example, a cooling
35 device may be placed about four inches up from the shoulder
blades and just below the nape of the neck and the spinal

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cord protrusions. As understood by persons of ordinary skill in the art, the precise location may vary depending on the size of the individual, the size of the patch, and the origin site of the hot flash. When the cooling device is
5 formed in a "T-shaped" configuration, the cooling device can be placed on the back in an upright configuration or an inverted configuration.

The cooling device can be effectively worn during the
10 day or during the night without causing discomfort to the wearer. During the day, the woman can wear the cooling device under her clothes without being noticed by other people. During the night, the woman can wear the patch to control night sweats and hot flashes.

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The cooling device is preferably secured to the woman's skin for more than one minute, and potentially for six or more hours. By placing the cooling device on the skin during the onset of a hot flash, the symptoms of the hot
20 flash can be effectively alleviated and prevented from spreading through the body. However, the cooling device 12 may be applied at any time a woman is experience a hot flash. Typically, the cooling device 12 is effective in controlling the hot flash symptoms within about 1 to about 2
25 minutes of contact with the skin.

The kit may be made by placing the cooling device and the instructions in a package, and sealing the package.

30 All references, articles, publications and patents and patent applications cited herein are incorporated by reference in their entirety.

While this invention has been described with respect to
35 various specific examples and embodiments, it is to be understood that the invention is not limited thereto and

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that it can be variously practiced within the scope of the following claims.